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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,182	01/10/2002	Frank Breitling	4121-126	8533

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/889,182	Applicant(s) BREITLING ET AL.	
	Examiner James L. Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 21-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-14 and 21-24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 07 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

AS

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 18 April 2005 is acknowledged and has been entered. Claims 21-24 are newly added. Claims 15-20 have been cancelled. Claims 1-14 and 21-24 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The drawings are objected to for the reasons that they appear informal and are not sufficiently clean and clear for publication. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Submission of corrected drawings may no longer be held in abeyance pending the indication of allowable subject matter. Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

The specification is objected to and claims 1-14 and 21-24 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record, set forth with regard to the prior similar subject matter of claims 1-14, that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth, one would not be assured of the ability to select the desired producer cell(s) from the population because, absent further guidance from applicant, one would be unable to identify and specifically separate the secreting cell(s) from a population of cells which are all capable of binding the secreted product.

Applicant's arguments filed 18 April 2005 have been fully considered but they are not deemed to be persuasive. Applicant urges that there is no likelihood that a non-secreting cell would present antibodies from another secreting cell in the invention because the cells are cloned at one cell per well. This is not found persuasive because the argument is entirely inconsistent with the disclosure of the invention. Although, as argued by applicant, cloning is notoriously old and well known in the art for conventional hybridoma selection, there is no disclosure of cloning cells before their selection in the instant invention. Indeed, the opposite is taught, for example on pages 8-9, wherein applicant teaches "[b]y means of the present invention... hybridoma cells do not have to be cultured separately. Complex mixtures of hybridoma cells can rather be used directly for selecting antibodies." The rejection is maintained.

The specification is objected to and claims 1-6 and 9-14 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record, that the specification does not reasonably provide enablement for expression of cell-surface antibody binding proteins, generally, other than those expressed by the particular exemplified expression vectors which function in the invention. For the reasons of record, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention

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commensurate in scope with these claims. As set forth, absent further written description and guidance from applicant, one would not be assured of the ability to perform the method with any predictability for any given fusion.

Applicant's arguments filed 18 April 2005 have been fully considered but they are not deemed to be persuasive. Applicant urges that the specification provides guidance for antibody binding protein and that the experimentation to make and use other of the suggested constructs for expression of other proteins would routine and would not be undue. This is not found persuasive for the reasons of record regarding the unpredictable nature of the experimentation, the unpredictable properties of the undefined constructs, the unpredictable function of the expressed products, and the unpredictability of the method generally for any given fusion event. The rejection is maintained.

The specification is objected to and claims 21-24, are rejected under 35 U.S.C. § 112, first paragraph, because the instant claims contain subject matter which was not described in the specification, as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention as is now claimed.

With regard to claims 21-24, the specification, as originally filed, does not provide support for a prior selection of anti-specific antigen antibody generating B-lymphocytes for fusion. Although one of skill in the art might realize from reading the disclosure that selected B lymphocytes are useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that selected B lymphocytes were originally

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contemplated as part of applicant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

Claims 1-14 and 21-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-14, "the exposure to the specific antigen" lacks antecedent basis.

In claims 21-24, it is believed that --Ig kappa-- was intended.

In claim 24, "FACS" should be --fluorescence-activated cell sorting (FACS)--.

Applicant's arguments filed 18 April 2005 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's implication to the contrary, rejections under this statute have not been obviated by applicant's amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

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A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

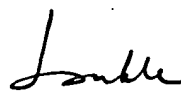
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


James L. Grun, Ph.D.
June 11, 2005


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/13/05